

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

GOWLING LAFLEUR HENDERSON LLP  
Suite 4900  
Commerce Court West  
Toronto, Ontario M5L 1J3  
CANADADate of mailing (day/month/year)  
15 October 2001 (15.10.01)Applicant's or agent's file reference  
5352-89

## IMPORTANT NOTIFICATION

International application No.  
PCT/CA00/01005International filing date (day/month/year)  
31 August 2000 (31.08.00)

## 1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

## Name and Address

BERESKIN & PARR  
40th Floor  
40 King Street West  
Toronto, Ontario M5H 3Y2  
Canada

## State of Nationality

## State of Residence

## Telephone No.

416 364 7311

## Facsimile No.

416 361 1398

## Teleprinter No.

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

## Name and Address

GOWLING LAFLEUR HENDERSON LLP  
Suite 4900  
Commerce Court West  
Toronto, Ontario M5L 1J3  
Canada

## State of Nationality

## State of Residence

## Telephone No.

416 364 7311

## Facsimile No.

416 361 1398

## Teleprinter No.

## 3. Further observations, if necessary:

New agent

## 4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned  
☐ the International Searching Authority ☒ the elected Offices concerned  
☐ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

## Authorized officer

Marie-José DEVILLARD

Telephone No.: (41-22) 338.83.38

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>5352-89</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/CA 00/ 01005</b>	International filing date (day/month/year) <b>31/08/2000</b>	(Earliest) Priority Date (day/month/year) <b>31/08/1999</b>
Applicant <b>CME TELEMETRIX INC.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

### 4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**METHOD OF CALIBRATING A SPECTROSCOPIC DEVICE**

### 5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

2  
☐ None of the figures.

# PATENT COOPERATION TREATY

RECEIVED

JUL 31 2001

BERESKIN & PARR

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BERESKIN & PARR  
40 King Street West, 40th Floor  
TORONTO, ONTARIO M5H 3Y2  
CANADA

RECEIVED

AUG 17 2001

GOWLINGS

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 26.07.2001

Applicant's or agent's file reference  
5352-89

## IMPORTANT NOTIFICATION

International application No.  
PCT/CA00/01005

International filing date (day/month/year)  
31/08/2000

Priority date (day/month/year)  
31/08/1999

Applicant  
CME TELEMETRIX INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

AUG - 1 2001

Name and mailing address of the IPEA/

 European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Weber, R

Tel. +49 89 2399-2382



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>5352-89</b>	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/CA00/01005</b>	International filing date (day/month/year) <b>31/08/2000</b>	Priority date (day/month/year) <b>31/08/1999</b>	
International Patent Classification (IPC) or national classification and IPC <b>G01N21/35</b>			
Applicant <b>CME TELEMETRIX INC.</b>			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  <b>20/02/2001</b>	Date of completion of this report  <b>26.07.2001</b>
Name and mailing address of the international preliminary examining authority:  <div style="display: flex; align-items: center;"> <div>             European Patent Office              D-80298 Munich              Tel. +49 89 2399 - 0 Tx: 523656 epmu d              Fax: +49 89 2399 - 4465           </div> </div>	Authorized officer  <b>Meyer, F</b>  Telephone No. +49 89 2399 2233



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA00/01005

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-15 as originally filed

**Claims, No.:**

1-11 as originally filed

**Drawings, sheets:**

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01005

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	2-10
	No:	Claims	1,11
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations  
see separate sheet

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
see separate sheet

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
see separate sheet

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA00/01005

1. Reference is made to the following documents:

D1: G.W. Small et al., Anal. Chem. **65** (1993) 3279-3289

D2: US 5 680 320

D3: US 5 606 164

D4: US 5 362 965

D5: US 5 576 544

**Re Item V**

2. The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of **claims 1 and 11**, as far as it can be understood (see paragraph 4. below), does not appear to involve an inventive step in the sense of Article 33(3) PCT.

2.1. Document D1, which is considered to represent the closest prior art, discloses a method of calibrating an NIR spectrometer for providing a non-invasive measurement of an analyte level in a sample (abstract, l.3-7; p.3279, right col., §3, l.2,8; p.3280, left col., §4, l.7 - p.3280, right col., §1, l.3), comprising: providing a plurality of calibration algorithms (p.3281, left col., §1, l.1-3; p.3282, left col., §3, l.1-3); taking a set of non-invasive measurements on said sample with said spectroscopic device (p.3281, left col., §1, l.3-6); calculating a set of analyte levels for each of the algorithms "in response to" the set of non-invasive measurements (p.3282, left col., §4, l.3-4; Fig.4), each of the sets of analyte levels "being characterized by" a variability range (see the columns "conc (mM)" in Table I on p.3280), a slope (see Fig.4), an " $R^2$ " (see Table III) and a standard error of prediction (p.3282, left col., §4, l.4-5; Table III); and selecting an appropriate calibration algorithm by using a "suitability score" based on the variability range (p.3281, left col., §1, l.10-12; p.3283, left col., §1 l.4-7) and the standard error of prediction for each of the sets of analyte levels (p.3282, left col., §4, l.7-9).

The subject-matter of independent **claim 1** of the present application differs from the method disclosed in D1 only in that, for selecting an appropriate calibration algorithm, a "suitability score" is used which is additionally based on the slope and " $R^2$ ".

The problem to be solved by the present invention may therefore be regarded as providing an improved "suitability score" for selecting an appropriate calibration algorithm.

The skilled person would contemplate combining the teaching of D1 with the teaching of D2 which also discloses a method of calibrating an NIR spectrometer (col.6 l.1,38-39). In D2, a calibration model is developed (see abstract, l.6) and it is explicitly stated that for a "very good validity and preciseness of the (calibration) model" (see col.11 l.66-67), "ideally,  $r^2$  (i.e. the unadjusted correlation coefficient), and  $k$  (i.e. the slope of the fit curves) should be as close to 1 as possible; while SEP (i.e. the standard error of prediction) ... should be as close to 0 as possible" (see col.11 l.63-65).

In view of the paragraph above, it would be obvious for the skilled person to additionally take into account the slope and " $r^2$ " when selecting an appropriate calibration algorithm. Thus, the subject-matter of **claim 1** does not appear to involve an inventive step and does not satisfy the criterion set forth in Articles 33(1) and 33(3) PCT.

- 2.2. Dependent **claim 11** does not appear to contain any additional feature which, in combination with the features of claim 1, meets the requirements of the PCT with respect to inventive step, since its additional feature is already disclosed in D1 (see p.3280, left col., §4, l.7 - p.3280, right col., l.3; p.3279, right col., §3, l.2,8).
- 2.3. Documents D3-D5 each disclose a method of calibrating a spectroscopic device for providing a non-invasive measurement of an analyte level in a sample comprising all the features of independent claim 1 of the present application, except that only the standard error of prediction (D3: col.13 l.61 - col.14 l.13), only the standard error of prediction and " $R$ " (D4: col.15 l.21-25) or only " $R^2$ " (D5: col.4 l.40-52) is used to select an appropriate calibration algorithm out of a plurality of provided calibration algorithms.
- Combination of the teachings of either D3, D4 or D5 with D2 appears to be obvious (Article 33(3) PCT) for reasons similar to those already pointed out in paragraph 2.1. above.
- 2.4. The subject-matter of dependent **claim 2** or dependent **claim 7** is neither disclosed nor hinted at in any of the available prior art documents. Both claims



hence would meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

- 2.5. **Claims 3-6 and 8-10** are dependent on claims 2 and 7, respectively, and therefore also satisfy the requirements of Article 33(1) PCT.

**Re Item VII**

- 3.1. Independent **claim 1** is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 3.2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.
- 3.3. In the description (p.7 l.34-35), the applicant incorporates by reference the disclosure of a US patent. If the applicant has the opinion, that the said disclosure contains matter which is essential for carrying out the invention as meant by Article 5 PCT, the applicant should expressly incorporate this matter into the description. Otherwise, this passage should be deleted from the description (see the PCT Guidelines II 4.17).
- 3.4. In order to make clear that the results shown in figures 1 and 4 are achieved using a known calibration method, the term "prior art" should be added to these figures.

**Re Item VIII**

4. The application does not meet the requirements of Article 6 PCT, because **claims 1, 7 and 8** are not clear.

- 4.1. In **claim 1** ("calculating a predicted set of analyte levels", p.16 l.8), it is not at all clear in what way the said set of analyte levels should be predicted.
- 4.2. Due to the vague formulation in **claim 1** "calculating a ... set of analyte levels ... in response to the set of non-invasive measurements" (p.16 l.8-10), it is not clear, whether (and how) the said measurements are used to calculate said set of analyte levels.
- 4.3. The formulation in **claim 1** "each of the predicted sets of analyte levels being characterized by a variability range, a slope, an  $R^2$  ... and a standard error of prediction" (p.16 l.10-13) does not include that the said variability range, slope,  $R^2$  and standard error of prediction are determined, but which appears to be essential for the proceeding "selection step" (p.16 l.14-17). The scope of the claim hence is obscure.
- 4.4. In **claim 1** the terms "variability range", "slope" and "standard error of prediction" are indefinite since they have not been defined in relation to any variable (see p.12 l.8, p.10 l.14-15, p.12 l.1-3).  
The term " $R^2$ " is indefinite, since the proceeding explanation given in brackets is not comprised in the subject-matter of the claim. Only reference numerals should be placed in brackets, see Rule 6.2(b) PCT. In this case, it appears that " $R^2$ " should be placed in brackets and said explanation should be incorporated into the text of the claim.  
Even further confusing is the fact that said explanation given in brackets contradicts the definition of "R" given in the description on p.12 l.10-11.
- 4.5. The feature "a suitability score based on the variability range, the slope, the  $R^2$  and the standard error of prediction ..." in **claim 1** (p.16 l.15-17) is obscure for several reasons:
- (i) The term "suitability score" does not appear to be a term well-known in the art. The skilled person would not know what has to be understood by this term.
  - (ii) The expression "a suitability score based on ..." is vague and indefinite.
  - (iii) The said feature furthermore contradicts the description (see p.12 l.26) where the only definition of a said "suitability score" is given, but without

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA00/01005

taking into account a said "variability range".

- 4.6. The feature "rejecting data sets that are not suitable for calibration" in **claim 7** (p.17 l.28) is indefinite since a criteria when to reject a said data set is missing.
- 4.7. The feature "parameters other than said analyte" in **claim 8** is vague and indefinite and as such renders the scope of the claim unclear.
5. The subject-matter of **claims 4-6 and 8** is not supported by the description as required by Article 6 PCT. A respective statement should have been added to the description (Rule 5.1(a)(iii) PCT).

RECEIVED

DEC 14 2000

BERESKIN &amp; PARR

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

120

(PCT Rule 44.1)

To:

BERESKIN & PARR  
40 King Street West, 40th Floor  
TORONTO, ONTARIO M5H 3Y2  
CANADADate of mailing  
(day/month/year)

12/12/2000

Applicant's or agent's file reference

5352-89

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/CA 00/ 01005

International filing date  
(day/month/year)

31/08/2000

Applicant

CME TELEMETRIX INC.

- 1.
- ☒
- The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

D.O. ENT. Feb. 12, 2001 FA

For more detailed instructions, see the notes on the accompanying sheet.

- 2.
- ☐
- The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

- 3.
- ☐
- With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

- 4.
- Further action(s):**
- The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Christine Voigt

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

**"Statement under article 19(1)" (Rule 46.4)**

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

**Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

**Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

## PATENT COOPERATION TREATY

207

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

BERESKIN & PARR  
40 King Street West  
40th floor  
Toronto, Ontario M5H 3Y2  
CANADA

DEC 27 2000

BERESKIN &amp; PARR

Date of mailing (day/month/year) 01 December 2000 (01.12.00)	
Applicant's or agent's file reference 5352-89	IMPORTANT NOTIFICATION
International application No. PCT/CA00/01005	International filing date (day/month/year) 31 August 2000 (31.08.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 31 August 1999 (31.08.99)
Applicant CME TELEMETRIX INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
31 Augu 1999 (31.08.99)	60/151,536	US	28 Nove 2000 (28.11.00)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Tessadel PAMPLIEGA

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38

6

RECEIVED

MAR 23 2001

BERESKIN & PARR

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BERESKIN & PARR  
40 King Street West, 40th Floor  
TORONTO, ONTARIO M5H 3Y2  
CANADA

NOTIFICATION OF RECEIPT  
OF DEMAND BY COMPETENT INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence  
and Administrative Instructions, Section 601(a))

Date of mailing  
(day/month/year)

14.03.01

Applicant's or agent's file reference

5352-69

IMPORTANT NOTIFICATION

International application No.

PCT/CA 00/ 01005

International filing date (day/month/year)

31/08/2000

Priority date (day/month/year)

31/08/1999

Applicant

CME TELEMETRIX INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

20/02/2001

2. This date of receipt is:

- ☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).  
☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).  
☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

- ☐ (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/

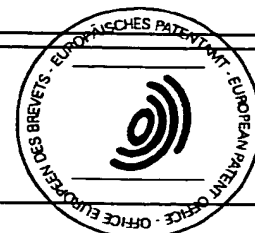


European Patent Office  
D-80298 Munich  
Tel. (+49-89) 2399-0, Tx: 523656 epmu d  
Fax: (+49-89) 2399-4465

Authorized officer

KAUFMANN S B

Tel. (+49-89) 2399-2975





# PATENT COOPERATION TREATY

WO 01/16579  
PCT/CA00/01005

PCT

## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

BERESKIN & PARR  
40 King Street West  
40th floor  
Toronto, Ontario M5H 3Y2  
CANADA

**RECEIVED**

MAR 21 2001

BERESKIN & PARR

Date of mailing (day/month/year) 08 March 2001 (08.03.01)		
Applicant's or agent's file reference 5352-89		
<b>IMPORTANT NOTICE</b>		
International application No. PCT/CA00/01005	International filing date (day/month/year) 31 August 2000 (31.08.00)	Priority date (day/month/year) 31 August 1999 (31.08.99)
Applicant CME TELEMETRIX INC. et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

CA,EP,JP

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 08 March 2001 (08.03.01) under No. WO 01/16579

### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer J. Zahra</p> <p>Telephone No. (41-22) 338.83.38</p>
---	---

# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

**PCT/CA** 00/01005  
International Application No.

**31** AUGUST 2000 (31.08.00)  
International Filing Date

**RO/CA**

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum) 5352-89

<b>Box No. I TITLE OF INVENTION</b>	
METHOD FOR IDENTIFICATION OF ALGORITHM FOR ANALYTE DETERMINATION	
<b>Box No. II APPLICANT</b>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
CME TELEMETRIX INC. 560 Parkside Drive Waterloo, Ontario N2L 5Z4 Canada	
<input type="checkbox"/> This person is also inventor.	
Telephone No. 519-886-8440	
Facsimile No. 519-886-8442	
Teleprinter No.	
State (that is, country) of nationality: CA	State (that is, country) of residence: CA
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<b>Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)</b>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
CADELL, Theodore E. 13 Elgin Street East Conestogo, Ontario N0B 1N0 Canada	
This person is: <input type="checkbox"/> applicant only <input checked="" type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality: CA	State (that is, country) of residence: CA
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<input type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
<b>Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE</b>	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
Bereskin & Parr 40 King Street West 40th Floor Toronto, Ontario, Canada M5H 3Y2	
Telephone No. (416) 364-7311	
Facsimile No. (416) 361-1398	
Teleprinter No.	
<input type="checkbox"/> Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

**Box No.V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

**Regional Patent**

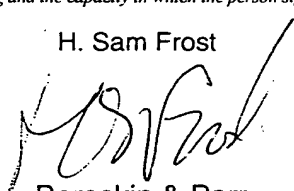
- ☐ **AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ **EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

**National Patent (if other kind of protection or treatment desired, specify on dotted line):**

- |   |   |
|---|---|
| <input type="checkbox"/> AE United Arab Emirates                  | <input type="checkbox"/> LC Saint Lucia                               |
| <input type="checkbox"/> AG Antigua and Barbuda                   | <input type="checkbox"/> LK Sri Lanka                                 |
| <input type="checkbox"/> AL Albania                               | <input type="checkbox"/> LR Liberia                                   |
| <input type="checkbox"/> AM Armenia                               | <input type="checkbox"/> LS Lesotho                                   |
| <input type="checkbox"/> AT Austria                               | <input type="checkbox"/> LT Lithuania                                 |
| <input type="checkbox"/> AU Australia                             | <input type="checkbox"/> LU Luxembourg                                |
| <input type="checkbox"/> AZ Azerbaijan                            | <input type="checkbox"/> LV Latvia                                    |
| <input type="checkbox"/> BA Bosnia and Herzegovina                | <input type="checkbox"/> MA Morocco                                   |
| <input type="checkbox"/> BB Barbados                              | <input type="checkbox"/> MD Republic of Moldova                       |
| <input type="checkbox"/> BG Bulgaria                              | <input type="checkbox"/> MG Madagascar                                |
| <input type="checkbox"/> BR Brazil                                | <input type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input type="checkbox"/> BY Belarus                               | <input type="checkbox"/> MN Mongolia                                  |
| <input type="checkbox"/> BZ Belize                                | <input type="checkbox"/> MW Malawi                                    |
| <input checked="" type="checkbox"/> CA Canada                     | <input type="checkbox"/> MX Mexico                                    |
| <input type="checkbox"/> CH and LI Switzerland and Liechtenstein  | <input type="checkbox"/> MZ Mozambique                                |
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| <input type="checkbox"/> CR Costa Rica                            | <input type="checkbox"/> NZ New Zealand                               |
| <input type="checkbox"/> CU Cuba                                  | <input type="checkbox"/> PL Poland                                    |
| <input type="checkbox"/> CZ Czech Republic                        | <input type="checkbox"/> PT Portugal                                  |
| <input type="checkbox"/> DE Germany                               | <input type="checkbox"/> RO Romania                                   |
| <input type="checkbox"/> DK Denmark                               | <input type="checkbox"/> RU Russian Federation                        |
| <input type="checkbox"/> DM Dominica                              | <input type="checkbox"/> SD Sudan                                     |
| <input type="checkbox"/> DZ Algeria                               | <input type="checkbox"/> SE Sweden                                    |
| <input type="checkbox"/> EE Estonia                               | <input type="checkbox"/> SG Singapore                                 |
| <input type="checkbox"/> ES Spain                                 | <input type="checkbox"/> SI Slovenia                                  |
| <input type="checkbox"/> FI Finland                               | <input type="checkbox"/> SK Slovakia                                  |
| <input type="checkbox"/> GB United Kingdom                        | <input type="checkbox"/> SL Sierra Leone                              |
| <input type="checkbox"/> GD Grenada                               | <input type="checkbox"/> TJ Tajikistan                                |
| <input type="checkbox"/> GE Georgia                               | <input type="checkbox"/> TM Turkmenistan                              |
| <input type="checkbox"/> GH Ghana                                 | <input type="checkbox"/> TR Turkey                                    |
| <input type="checkbox"/> GM Gambia                                | <input type="checkbox"/> TT Trinidad and Tobago                       |
| <input type="checkbox"/> HR Croatia                               | <input type="checkbox"/> TZ United Republic of Tanzania               |
| <input type="checkbox"/> HU Hungary                               | <input type="checkbox"/> UA Ukraine                                   |
| <input type="checkbox"/> ID Indonesia                             | <input type="checkbox"/> UG Uganda                                    |
| <input type="checkbox"/> IL Israel                                | <input checked="" type="checkbox"/> US United States of America       |
| <input type="checkbox"/> IN India                                 | <input type="checkbox"/> UZ Uzbekistan                                |
| <input type="checkbox"/> IS Iceland                               | <input type="checkbox"/> VN Viet Nam                                  |
| <input checked="" type="checkbox"/> JP Japan                      | <input type="checkbox"/> YU Yugoslavia                                |
| <input type="checkbox"/> KE Kenya                                 | <input type="checkbox"/> ZA South Africa                              |
| <input type="checkbox"/> KG Kyrgyzstan                            | <input type="checkbox"/> ZW Zimbabwe                                  |
| <input type="checkbox"/> KP Democratic People's Republic of Korea |   |
| <input type="checkbox"/> KR Republic of Korea                     |   |
| <input type="checkbox"/> KZ Kazakhstan                            |   |

Check-box reserved for designating States which have become party to the PCT after issuance of this sheet:

**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

<b>Box No. VI PRIORITY CLAIM</b>		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1) 31 August 1999 31.08.99	60/151,536	US		
item (2)				
item (3)				
<input type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s):				
* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.				
<b>Box No. VII INTERNATIONAL SEARCHING AUTHORITY</b>				
<b>Choice of International Searching Authority (ISA)</b> (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):		<b>Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):</b> Date (day/month/year)      Number      Country (or regional Office)		
ISA / EPO				
<b>Box No. VIII CHECK LIST; LANGUAGE OF FILING</b>				
This international application contains the following number of sheets: request : 3 description (excluding sequence listing part) : 15 claims : 3 abstract : 1 drawings : 5 sequence listing part of description : Total number of sheets : 27		This international application is accompanied by the item(s) marked below: 1. <input type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input type="checkbox"/> other (specify):		
Figure of the drawings which should accompany the abstract: FIG. 2		Language of filing of the international application: English		
<b>Box No. IX SIGNATURE OF APPLICANT OR AGENT</b>				
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).				
H. Sam Frost  Bereskin & Parr Agents for the Applicant				

For receiving Office use only		2. Drawings: <input checked="" type="checkbox"/> received:  <input type="checkbox"/> not received:
1. Date of actual receipt of the purported international application: 31 AUGUST 2000 (31.08.00)		
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		
4. Date of timely receipt of the required corrections under PCT Article 11(2):		
5. International Searching Authority (if two or more are competent): ISA /	6. <input checked="" type="checkbox"/> Transmittal of search copy delayed until search fee is paid.	

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

## INTERNATIONAL SEARCH REPORT

International Application No

CA 00/01005

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SMALL G W ET AL: "STRATEGIES FOR COUPLING DIGITAL FILTERING WITH PARTIAL LEAST-SQUARES REGRESSION: APPLICATION TO THE DETERMINATION OF GLUCOSE IN PLASMA BY FOURIER TRANSFORM NEAR-INFRARED SPECTROSCOPY" ANALYTICAL CHEMISTRY,US,AMERICAN CHEMICAL SOCIETY. COLUMBUS, vol. 65, no. 22, 15 November 1993 (1993-11-15), pages 3279-3289, XP000503258 ISSN: 0003-2700	1,11
A	page 3279, right-hand column -page 3283, left-hand column; figure 4; tables 1,3 abstract  --- -/--	7,9,10

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

29 November 2000

Date of mailing of the international search report

12/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Meyer, F

## INTERNATIONAL SEARCH REPORT

International Application No

CA 00/01005

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 680 320 A (HELMER ULLA ET AL) 21 October 1997 (1997-10-21)	1, 11
A	column 5, line 65 -column 6, line 67 abstract; figures 1-5 ---	2, 9, 10
A	US 5 606 164 A (PRICE JOHN F ET AL) 25 February 1997 (1997-02-25) column 2, line 58 -column 7, line 37 abstract; figures 11, 12, 15 ---	1, 7-11
A	US 5 362 965 A (MAGGARD STEVEN M) 8 November 1994 (1994-11-08) column 4, line 47 -column 6, line 54 abstract; table 7 ---	1, 2, 7, 9, 10
A	US 5 576 544 A (ROSENTHAL ROBERT D) 19 November 1996 (1996-11-19) column 2, line 43-57 abstract; figure 1 ---	1, 7, 8, 10, 11
A	WO 99 34193 A (ATHERTON PHILIP GWYTHIER ; BROTHERTON GEORGE ALEXANDER (AU); LETHBRI) 8 July 1999 (1999-07-08) page 7; tables 1-8 abstract -----	1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

CA 00/01005

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5680320 A	21-10-1997	AT 165446 T	15-05-1998
		AT 161631 T	15-01-1998
		AU 2582395 A	05-12-1995
		AU 2582495 A	05-12-1995
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		DE 69501333 D	05-02-1998
		DE 69501333 T	16-04-1998
		DE 69502189 D	28-05-1998
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		FI 960243 A	17-01-1997
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		JP 10500216 T	06-01-1998
		SE 9401718 A	19-11-1995
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		WO 9531714 A	23-11-1995
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		AU 6644896 A	05-03-1997
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		EP 0846253 A	10-06-1998
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		WO 9706418 A	20-02-1997
US 5362965 A	08-11-1994	AT 164674 T	15-04-1998
		AU 3665393 A	30-12-1993
		BR 9305937 A	02-05-1995
		CA 2127546 A	09-12-1993
		DE 69317777 D	07-05-1998
		DE 69317777 T	22-10-1998
		EP 0642660 A	15-03-1995
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		AU 8238791 A	23-01-1992
		CA 2086019 A,C	28-12-1991
		DE 69123448 D	16-01-1997

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

CA 00/01005

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5576544 A		DE 69123448 T	22-05-1997
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		NZ 238717 A	26-08-1994
		WO 9200513 A	09-01-1992
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		US 5218207 A	08-06-1993
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		BR 9814406 A	10-10-2000
		ZA 9811783 A	22-06-1999



## INTERNATIONAL SEARCH REPORT

International Application No.

CT/CA 00/01005

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 G01N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SMALL G W ET AL: "STRATEGIES FOR COUPLING DIGITAL FILTERING WITH PARTIAL LEAST-SQUARES REGRESSION: APPLICATION TO THE DETERMINATION OF GLUCOSE IN PLASMA BY FOURIER TRANSFORM NEAR-INFRARED SPECTROSCOPY" ANALYTICAL CHEMISTRY, US, AMERICAN CHEMICAL SOCIETY. COLUMBUS, vol. 65, no. 22, 15 November 1993 (1993-11-15), pages 3279-3289, XP000503258 ISSN: 0003-2700	1,11
A	page 3279, right-hand column -page 3283, left-hand column; figure 4; tables 1,3 abstract --- -/--	7,9,10

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
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- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*8\* document member of the same patent family

Date of the actual completion of the international search

29 November 2000

Date of mailing of the international search report

12/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Meyer, F

## INTERNATIONAL SEARCH REPORT

International Application No

T/CA 00/01005

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 680 320 A (HELMER ULLA ET AL) 21 October 1997 (1997-10-21)	1,11
A	column 5, line 65 -column 6, line 67 abstract; figures 1-5 ---	2,9,10
A	US 5 606 164 A (PRICE JOHN F ET AL) 25 February 1997 (1997-02-25) column 2, line 58 -column 7, line 37 abstract; figures 11,12,15 ---	1,7-11
A	US 5 362 965 A (MAGGARD STEVEN M) 8 November 1994 (1994-11-08) column 4, line 47 -column 6, line 54 abstract; table 7 ---	1,2,7,9, 10
A	US 5 576 544 A (ROSENTHAL ROBERT D) 19 November 1996 (1996-11-19) column 2, line 43-57 abstract; figure 1 ---	1,7,8, 10,11
A	WO 99 34193 A (ATHERTON PHILIP GWYTH ;BROTHERTON GEORGE ALEXANDER (AU); LETHBRI) 8 July 1999 (1999-07-08) page 7; tables 1-8 abstract -----	1

## INTERNATIONAL SEARCH REPORT

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International Application No

T/CA 00/01005

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		AT 161631 T	15-01-1998
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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/CA 00/01005A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 601N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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A	page 3279, right-hand column -page 3283, left-hand column; figure 4; tables 1, 3 abstract  --- -/--	7, 9, 10

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Date of the actual completion of the international search

29 November 2000

Date of mailing of the international search report

12/12/2000

Name and mailing address of the ISA

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Fax (+31-70) 340-3016

Authorized officer

Meyer, F

## INTERNATIONAL SEARCH REPORT

Int Application No

PCT/CA 00/01005

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 680 320 A (HELMER ULLA ET AL) 21 October 1997 (1997-10-21)	1, 11
A	column 5, line 65 -column 6, line 67 abstract; figures 1-5	2, 9, 10
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		CA 2086019 A,C	28-12-1991
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# INTERNATIONAL SEARCH REPORT

...on patent family members

1st Application No

PCT/CA 00/01005

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5576544 A		DE 69123448 T	22-05-1997
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		BR 9814406 A	10-10-2000
		ZA 9811783 A	22-06-1999



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA00/01005

taking into account a said "variability range".

- 4.6. The feature "rejecting data sets that are not suitable for calibration" in **claim 7** (p.17 l.28) is indefinite since a criteria when to reject a said data set is missing.
- 4.7. The feature "parameters other than said analyte" in **claim 8** is vague and indefinite and as such renders the scope of the claim unclear.
5. The subject-matter of **claims 4-6 and 8** is not supported by the description as required by Article 6 PCT. A respective statement should have been added to the description (Rule 5.1(a)(iii) PCT).

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>5352-89</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/CA 00/ 01005</b>	International filing date (day/month/year) <b>31/08/2000</b>	(Earliest) Priority Date (day/month/year) <b>31/08/1999</b>
Applicant <b>CME TELEMETRIX INC.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**METHOD OF CALIBRATING A SPECTROSCOPIC DEVICE**

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

2

☐ None of the figures.

PATENT COOPERATION

EATY

PCT

REC'D 30 JUL 2001

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5352-89	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA00/01005	International filing date (day/month/year) 31/08/2000	Priority date (day/month/year) 31/08/1999
International Patent Classification (IPC) or national classification and IPC G01N21/35		
Applicant CME TELEMETRIX INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 8 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 20/02/2001	Date of completion of this report 26.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Meyer, F Telephone No. +49 89 2399 2233 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01005

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-15 as originally filed

**Claims, No.:**

1-11 as originally filed

**Drawings, sheets:**

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA00/01005

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims 1-11
	No: Claims
Inventive step (IS)	Yes: Claims 2-10
	No: Claims 1,11
Industrial applicability (IA)	Yes: Claims 1-11
	No: Claims

2. Citations and explanations  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

1. Reference is made to the following documents:

D1: G.W. Small et al., Anal. Chem. **65** (1993) 3279-3289  
D2: US 5 680 320  
D3: US 5 606 164  
D4: US 5 362 965  
D5: US 5 576 544

**Re Item V**

2. The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of **claims 1 and 11**, as far as it can be understood (see paragraph 4. below), does not appear to involve an inventive step in the sense of Article 33(3) PCT.
- 2.1. Document D1, which is considered to represent the closest prior art, discloses a method of calibrating an NIR spectrometer for providing a non-invasive measurement of an analyte level in a sample (abstract, l.3-7; p.3279, right col., §3, l.2,8; p.3280, left col., §4, l.7 - p.3280, right col., §1, l.3), comprising: providing a plurality of calibration algorithms (p.3281, left col., §1, l.1-3; p.3282, left col., §3, l.1-3); taking a set of non-invasive measurements on said sample with said spectroscopic device (p.3281, left col., §1, l.3-6); calculating a set of analyte levels for each of the algorithms "in response to" the set of non-invasive measurements (p.3282, left col., §4, l.3-4; Fig.4), each of the sets of analyte levels "being characterized by" a variability range (see the columns "conc (mM)" in Table I on p.3280), a slope (see Fig.4), an " $R^2$ " (see Table III) and a standard error of prediction (p.3282, left col., §4, l.4-5; Table III); and selecting an appropriate calibration algorithm by using a "suitability score" based on the variability range (p.3281, left col., §1, l.10-12; p.3283, left col., §1 l.4-7) and the standard error of prediction for each of the sets of analyte levels (p.3282, left col., §4, l.7-9). The subject-matter of independent **claim 1** of the present application differs from the method disclosed in D1 only in that, for selecting an appropriate calibration algorithm, a "suitability score" is used which is additionally based on the slope and " $R^2$ ".

The problem to be solved by the present invention may therefore be regarded as providing an improved "suitability score" for selecting an appropriate calibration algorithm.

The skilled person would contemplate combining the teaching of D1 with the teaching of D2 which also discloses a method of calibrating an NIR spectrometer (col.6 l.1,38-39). In D2, a calibration model is developed (see abstract, l.6) and it is explicitly stated that for a "very good validity and preciseness of the (calibration) model" (see col.11 l.66-67), "ideally,  $r^2$  (i.e. the unadjusted correlation coefficient), and k (i.e. the slope of the fit curves) should be as close to 1 as possible; while SEP (i.e. the standard error of prediction) ... should be as close to 0 as possible" (see col.11 l.63-65).

In view of the paragraph above, it would be obvious for the skilled person to additionally take into account the slope and " $r^2$ " when selecting an appropriate calibration algorithm. Thus, the subject-matter of **claim 1** does not appear to involve an inventive step and does not satisfy the criterion set forth in Articles 33(1) and 33(3) PCT.

- 2.2. Dependent **claim 11** does not appear to contain any additional feature which, in combination with the features of claim 1, meets the requirements of the PCT with respect to inventive step, since its additional feature is already disclosed in D1 (see p.3280, left col., §4, l.7 - p.3280, right col., l.3; p.3279, right col., §3, l.2,8).
- 2.3. Documents D3-D5 each disclose a method of calibrating a spectroscopic device for providing a non-invasive measurement of an analyte level in a sample comprising all the features of independent claim 1 of the present application, except that only the standard error of prediction (D3: col.13 l.61 - col.14 l.13), only the standard error of prediction and "R" (D4: col.15 l.21-25) or only " $R^2$ " (D5: col.4 l.40-52) is used to select an appropriate calibration algorithm out of a plurality of provided calibration algorithms.
- Combination of the teachings of either D3, D4 or D5 with D2 appears to be obvious (Article 33(3) PCT) for reasons similar to those already pointed out in paragraph 2.1. above.
- 2.4. The subject-matter of dependent **claim 2** or dependent **claim 7** is neither disclosed nor hinted at in any of the available prior art documents. Both claims

hence would meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

- 2.5. **Claims 3-6 and 8-10** are dependent on claims 2 and 7, respectively, and therefore also satisfy the requirements of Article 33(1) PCT.

**Re Item VII**

- 3.1. Independent **claim 1** is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 3.2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.
- 3.3. In the description (p.7 l.34-35), the applicant incorporates by reference the disclosure of a US patent. If the applicant has the opinion, that the said disclosure contains matter which is essential for carrying out the invention as meant by Article 5 PCT, the applicant should expressly incorporate this matter into the description. Otherwise, this passage should be deleted from the description (see the PCT Guidelines II 4.17).
- 3.4. In order to make clear that the results shown in figures 1 and 4 are achieved using a known calibration method, the term "prior art" should be added to these figures.

**Re Item VIII**

4. The application does not meet the requirements of Article 6 PCT, because **claims 1, 7 and 8** are not clear.



- 4.1. In **claim 1** ("calculating a predicted set of analyte levels", p.16 l.8), it is not at all clear in what way the said set of analyte levels should be predicted.
- 4.2. Due to the vague formulation in **claim 1** "calculating a ... set of analyte levels ... in response to the set of non-invasive measurements" (p.16 l.8-10), it is not clear, whether (and how) the said measurements are used to calculate said set of analyte levels.
- 4.3. The formulation in **claim 1** "each of the predicted sets of analyte levels being characterized by a variability range, a slope, an  $R^2$  ... and a standard error of prediction" (p.16 l.10-13) does not include that the said variability range, slope,  $R^2$  and standard error of prediction are determined, but which appears to be essential for the proceeding "selection step" (p.16 l.14-17). The scope of the claim hence is obscure.
- 4.4. In **claim 1** the terms "variability range", "slope" and "standard error of prediction" are indefinite since they have not been defined in relation to any variable (see p.12 l.8, p.10 l.14-15, p.12 l.1-3).  
The term " $R^2$ " is indefinite, since the proceeding explanation given in brackets is not comprised in the subject-matter of the claim. Only reference numerals should be placed in brackets, see Rule 6.2(b) PCT. In this case, it appears that " $R^2$ " should be placed in brackets and said explanation should be incorporated into the text of the claim.  
Even further confusing is the fact that said explanation given in brackets contradicts the definition of "R" given in the description on p.12 l.10-11.
- 4.5. The feature "a suitability score based on the variability range, the slope, the  $R^2$  and the standard error of prediction ..." in **claim 1** (p.16 l.15-17) is obscure for several reasons:
- (i) The term "suitability score" does not appear to be a term well-known in the art. The skilled person would not know what has to be understood by this term.
  - (ii) The expression "a suitability score based on ..." is vague and indefinite.
  - (iii) The said feature furthermore contradicts the description (see p.12 l.26) where the only definition of a said "suitability score" is given, but without